REMARKS

Claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, 103-105, and 109-111 are presently pending in the case. Claims 1-37, 40, 42, 43, 45, 46, 57, 59, 61, 69-102 and 106-108 have been cancelled without prejudice or disclaimer. Claims 38, 54, 104 and 105 have been amended. Claims 109-111 have been added. The amendments and new claims are supported by the specification and claims as originally filed.

Reconsideration of the present case in view of the above amendments and the remarks herein is requested.

Claim rejections under 35 USC §112

The Examiner rejected claim 104 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Examiner's objection to the language in claim 104 is believed to be overcome by the above amendment. Withdrawal of the rejection is requested.

Claim rejections under judicially created doctrine of Double Patenting

The Examiner provisionally rejected claims 38, 39, 41, 44, 47-56, 58, 60, 62-68, and 103-105 under the judicially created doctrine of double patenting as being unpatentable over the claims of U.S. Patent Application 11/187,757.

Upon the indication of allowable claims, Applicant will consider the propriety of filing a terminal disclaimer in compliance with 37 CFR 1.321(c) in accordance with the Examiner's suggestion.

Claim rejections under 35 USC 103(a)

The Examiner rejected claims 38, 39, 41, 44, 47-56, 58, 60, 62-68 and 103-105 under 35 USC §103(a) as being unpatentable over US Patent Application 2002/0037316 to Weers et al (hereinafter Weers et al) in view of US Patent Application 2002/0177562 to Weickert et al (hereinafter Weickert et al), the journal article to Wiedmann et al (hereinafter Weidmann et al), and PCT Patent Application WO 00/01365 to Didriksen (hereinafter Didriksen). The rejection is traversed.

Weers et al, Weickert et al, Wiedmann et al, and Didriksen do not render independent claim 38 unpatentable. Claim 38 is to a pharmaceutical formulation comprising particulates comprising active agent particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose. Weers et al does not disclose particulates comprising active agent particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose. Instead, Weers et al discloses particulates where a solution of an active agent (as opposed to particles of active agent) is dispersed within a phospholipid matrix. In one example, Weers et al discloses budesonide particles within a matrix (see Example V). However, in this example, the budesonide is combined with lactose (see page 12 lines 1-4). Claim 38 explicitly excludes lactose-containing particles from its ambit. Accordingly, Weers et al does not disclose, teach or suggest the invention as set forth in claim 38. Weickert et al, Weidmann et al, and Didriksen do not make up for the deficiencies of Weers et al. Therefore, the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a).

For at least these reasons, claim 38 is not properly rejectable under 35 USC §103(a) as being unpatentable over Weers et al, Weickert et al, Wiedmann et al, and Didriksen. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Weickert

et al, Wiedmann et al, and Didriksen could be applied, with a reasonable likelihood of success, to Weers et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 38 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 38 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 38 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 39, 41, 44, 47-53 and 103 which depend from claim 38 and are not rendered unpatentable by Weers et al, Weickert et al, Wiedmann et al, and Didriksen for at least the same reasons as claim 38.

In addition, Weers et al, Weickert et al, Wiedmann et al, and Didriksen do not render independent claim 54 unpatentable. Claim 54 is to a pharmaceutical formulation comprising particulates comprising amphotericin B particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose. Weers et al does not disclose particulates comprising active agent particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose. Instead, Weers et al discloses particulates where a solution of an active agent (as opposed to particles of active agent) is dispersed within a phospholipid matrix. In one example, Weers et al discloses budesonide particles within a matrix (see Example V). However, in this example, the budesonide is combined with lactose (see page 12 lines 1-4). Claim 54 explicitly excludes lactose-containing particles from its ambit. Accordingly, Weers et al does not disclose, teach or suggest the invention as set forth in claim 54. Weickert et al, Weidmann et al, and Didriksen do not make up for the deficiencies of Weers et al. Therefore, the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a).

For at least these reasons, claim 54 is not properly rejectable under 35 USC §103(a) as being unpatentable over Weers et al, Weickert et al, Wiedmann et al, and Didriksen. The modification proposed by the Examiner is not one that would have been

well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Weickert et al, Wiedmann et al, and Didriksen could be applied, with a reasonable likelihood of success, to Weers et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 54 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 54 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 54 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claims 55, 56, 58, 60 and 62-68 which depend from claim 38 and are not rendered unpatentable by Weers et al, Weickert et al, Wiedmann et al, and Didriksen for at least the same reasons as claim 54.

Weers et al, Weickert et al, Wiedmann et al, and Didriksen do not render independent claim 104 unpatentable, either. Claim 104 is to a pharmaceutical formulation comprising an active agent particle in a phospholipid matrix, wherein the particulates do not comprise lactose. Weers et al does not disclose particulates comprising active agent particles in a matrix comprising a phospholipid, wherein the particulates do not comprise lactose. Instead, Weers et al discloses particulates where a solution of an active agent (as opposed to particles of active agent) is dispersed within a phospholipid matrix. In one example, Weers et al discloses budesonide particles within a matrix (see Example V). However, in this example, the budesonide is combined with lactose (see page 12 lines 1-4). Claim 104 explicitly excludes lactose-containing particles from its ambit. Accordingly, Weers et al does not disclose, teach or suggest the invention as set forth in claim 104. Weickert et al, Weidmann et al, and Didriksen do not make up for the deficiencies of Weers et al. Therefore, the Examiner has failed to establish a prima facie case under 35 U.S.C. §103(a).

For at least these reasons, claim 104 is not properly rejectable under 35 USC §103(a) as being unpatentable over Weers et al, Weickert et al, Wiedmann et al, and

Didriksen. The modification proposed by the Examiner is not one that would have been well within the grasp of one of ordinary skill in the art at the time the invention was made. In this regard, the Examiner has failed to establish that the teachings of Weickert et al, Wiedmann et al, and Didriksen could be applied, with a reasonable likelihood of success, to Weers et al. There is no evidence to suggest that this is a situation where the ordinary artisan could have combined in the teachings in a manner that would result in the invention of claim 104 and there is no evidence to suggest the artisan would have seen the benefit in doing so. Thus, claim 104 is allowable over the references cited.

Applicant requests withdrawal of the rejection of claim 104 under 35 U.S.C. §103(a). In addition, Applicant requests withdrawal of the rejection of claim 105 which depends from claim 104 and is not rendered unpatentable by Weers et al, Weickert et al, Wiedmann et al, and Didriksen for at least the same reasons as claim 104.

Conclusion

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

JANAH & ASSOCIATES

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